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Safety

Recall -- Firm Press Release

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Defibtech Announces a Voluntary Recall of DBP-2800 Battery Packs used in the Lifeline AED[®] and ReviveR AED[™]

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FOR IMMEDIATE RELEASE - June 03, 2010 - Guilford, CT – Defibtech, LLC, is initiating a voluntary recall of 5,418 DBP-2800 Battery Packs used in the Lifeline AED[®] and ReviveR AED[™] (semi-automatic external defibrillators). This recall affects all DBP- 2800 Battery Packs shipped prior to June 4, 2007. In rare instances, when the AED is used with an affected battery pack, the AED may falsely detect an error condition during charging for a shock, then cancel charge and not provide therapy. Defibtech determined the need for this recall after learning of four reports from end users of this malfunction during patient use.

The company has identified recommendations for the end customer to follow until the battery pack has been corrected, which allows the battery pack to remain in service. A copy of these recommendations is being mailed to all affected customers. This customer notification, as well as instructions on determining whether a battery pack is affected, can also be found on the www.defibtech.com/batteryFA¹ web page. For additional information regarding this recall, please refer to the above referenced web page, contact your distributor, or contact Defibtech at techsupport@defibtech.com, 1-877-453-4507 or 1- 203-453-4507.

Defibtech will provide customers with a free battery pack update card to address this issue for all affected battery packs. The correction to the battery pack will be able to be performed at the location where the battery pack is deployed using any DDU-100 series AED and a Defibtech supplied battery pack update card. The battery pack update is expected to be available within the next two weeks.

The DBP-2800 battery packs affected by this recall have been distributed globally to fire departments, EMS, health clubs, schools, and other organizations. The affected battery packs are used in AEDs which can be identified by the words "Lifeline AED[®]" and "ReviveR AED[™]" on the front of the device.

The Food and Drug Administration (FDA) has determined that this action is a Class I recall. Any adverse reactions experienced with the use of this product and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800- FDA-1088, or on the MedWatch website at www.fda.gov/medwatch².

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